**AMENDMENTS TO THE CLAIMS** 

This listing of claims will replace all prior versions, and listings, of claims in the present

application.

**Listing of Claims:** 

1. (Currently Amended) A sustained-release preparation which comprises:

a drug having a molecular weight of about 10,000 or less; and

a gelatin hydrogel,

wherein the drug is impregnated into said gelatin hydrogel through a surface thereof and

is immobilized in said hydrogel by physiochemical interaction, and

said hydrogel having a concentration gradient of the drug such that said concentration

gradient being higher at said surface than in other parts of said hydrogel in said sustained-release

preparation, and the drug is immobilized within said hydrogel by said physiochemical

interaction, thereby controlling the directionality of the sustained release of the drug upon

administration of the sustained-release preparation, and

said sustained-release preparation is sterile.

2. (Canceled)

3. (Previously Presented) A method of sustained release of a drug in vivo comprising:

administering a sustained-release preparation to a patient in need thereof, said preparation

comprising a drug having a molecular weight of about 10,000 or less and a gelatin hydrogel,

wherein said hydrogel has a concentration gradient of the drug in said sustained-release preparation, wherein degradation of the gelatin hydrogel *in vivo* causes more drug to be released from a region with higher drug concentration, thereby giving said sustained release of the drug, wherein the drug is impregnated into said gelatin hydrogel through a surface thereof and is immobilized in said hydrogel by physiochemical interaction, said concentration gradient being higher at said surface than in other parts of said hydrogel, and said sustained-release preparation is sterile.

- 4. (Previously Presented) The method of claim 3, where said administration is topical.
- 5. (**Previously Presented**) The sustained-release preparation of claim 1, wherein the drug is impregnated into said gelatin hydrogel by ionic bonding.
- 6. (**Previously Presented**) The sustained-release preparation of claim 1, wherein the preparation is in solid or semi-solid form.
  - 7. (Previously Presented) A sustained-release preparation which comprises:
  - a drug having a molecular weight of about 10,000 or less; and
  - a crosslinked gelatin hydrogel,

said sustained-release preparation being made by adding an aqueous solution of said drug dropwise to said crosslinked gelatin hydrogel, thereby impregnating said drug into said crosslinked gelatin hydrogel through a surface thereof, immobilizing said drug in said

Art Unit 1615

**Supplemental Amendment** 

crosslinked gelatin hydrogel by physiochemical interaction between said drug and crosslinked

gelatin hydrogel, and forming a concentration gradient of the drug in the crosslinked gelatin

hydrogel such that said concentration gradient is higher at said surface than in other parts of said

hydrogel in said sustained-release preparation, wherein the amount of aqueous solution being

added dropwise causes swelling of the crosslinked gelatin hydrogel and wherein said sustained-

release preparation is sterile.

8-10. (Canceled)

11. (New) The sustained-release preparation of claim 1, in a form suitable for topical

application.

12. (New) The sustained-release preparation of claim 7, in a form suitable for topical

application.

13. (New) The sustained-release preparation of claim 1, which is in a solid or semisolid

single dose form containing 0.01 to 10,000 µg of said drug.

14. (New) The method of claim 3, wherein said sustained release preparation is in a solid

or semisolid single dose form containing 0.01 to 10,000 µg of said drug.

5 of 10 GMM/ETP/

Supplemental Amendment

15. (New) The sustained-release preparation of claim 7, in a solid or semisolid single

dose form containing 0.01 to 10,000 µg of said drug.

16. (New) The sustained-release preparation of claim 1, which is in a solid single dose

Docket No.: 3691-0122PUS1

form containing 0.1 to 1,000 µg of said drug.

17. (New) The method of claim 3, wherein said sustained release preparation is in a solid

single dose form containing 0.1 to 1,000 µg of said drug.

18. (New) The sustained-release preparation of claim 7, in a solid single dose form

containing 0.1 to 1,000 µg of said drug.

6 of 10 GMM/ETP/